PCA

CLINICIAN MANUAL

ambIT®

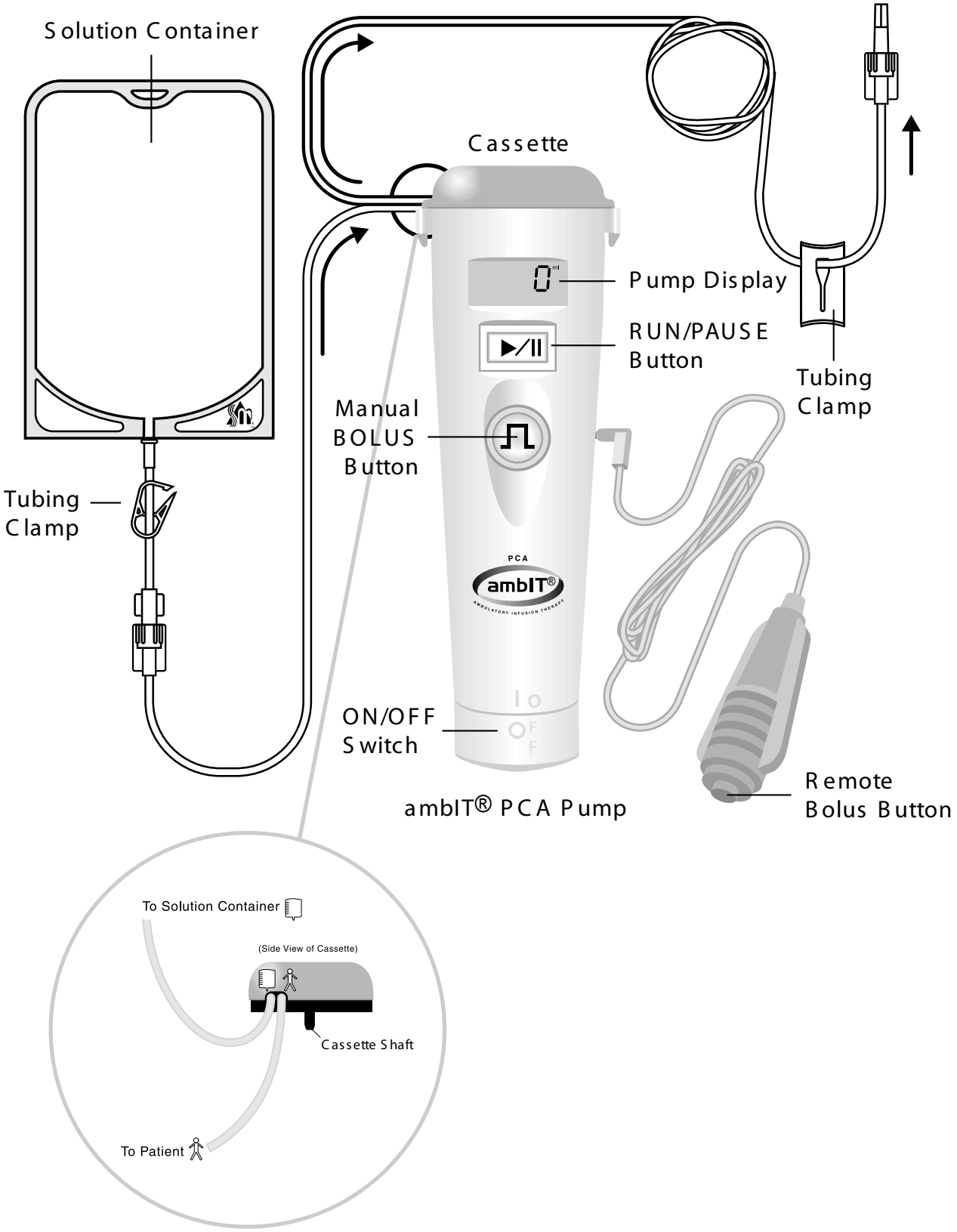
AMBULATORY INFUSION THERAPY

MORE THAN PAIN RELIEF…
SUPERIOR PAIN CONTROL

CE 0482 TYPE BF NRTL/C IPX1

SORENSON MEDICAL

Become Familiar with the ambIT® Pump and Cassette



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SECTION 1
INTRODUCTION

1.1 Definitions and Symbols

Warning:
A warning message contains special safety emphasis and must be observed at all times. Failure to observe a WARNING message is potentially life threatening.

Caution:
A caution usually appears in front of a procedure or statement. Failure to observe a CAUTION could result in serious patient or user injury.

Note:
A note highlights information that acts as a reminder or helps explain a concept or procedure.

This international symbol means: Attention, consult accompanying documents.

IPX1

Protected from dripping water.

TYPE BF

This is the IEC symbol for TYPE BF equipment.

- IEC Classification Internally Powered.

PCA ambIT® AMBULATORY INFUSION THERAPY

- The ambIT® PCA Pump complies with EN 60601-1:1990 including amendments A1 and A2; IEC 60601-1:1998; IEC 60601-2-24:1998; CAN/CSA C22.2 No. 601-M90 with supplement No. 1-94; UL2601-1:1997 with amendments 1 and 2.

CE 0482

This CE symbol certifies that the product complies with the essential requirements of the Medical Device Directive.

NRTL/C

The “NRTL/C” indicator adjacent to the CSA (Canadian Standards Association) Mark signifies the product has been evaluated to the applicable ANSI/UL and CSA standards, for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S.Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

Do not re-use (Cassettes)

Keep away from heat

Keep dry

Temperature limitation

STERILE R Sterilized using irradiation

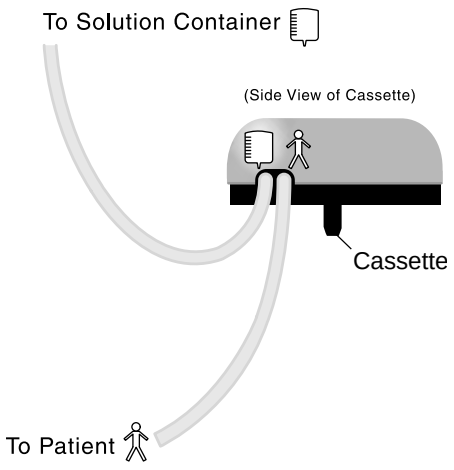
LATEX-free

Indicates which tubing connects to the solution container

Indicates which tubing connects to the patient

Bolus

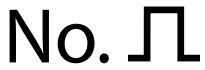
Program Lockout



Bolus Lockout Time in hours : minutes

Bolus Volume in milliliters

Basal Infusion Rate in ml/hr



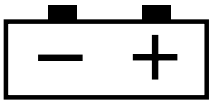
Number of Boluses Delivered

Number of Bolus Requests

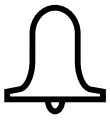
Volume to be Infused

RUN/PAUSE Button

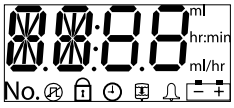
BOLUS Button



Low/Dead Battery Indicator



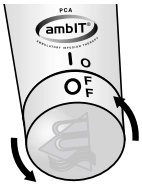
Alarm Indicator

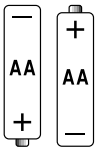


ambIT™ PCA Pump Display

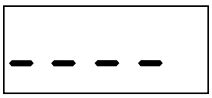
Pump Power ON

Pump Power OFF





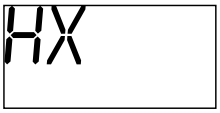
Battery Orientation



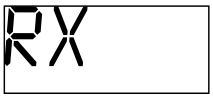
Program Lockout Code

Program Lock Mode

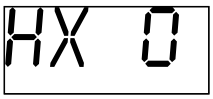
Pump Program Mode



Infusion History Report



Review Pump Program



Pump Infusion History Cleared

1.2 Warnings

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

This product should only be used by a physician or by a trained individual under direct supervision of a physician.

Read instructions before use. The Pump must be used strictly in accordance with these instructions.

Safe use of this Pump is the primary responsibility of the user. The user is responsible for monitoring this Pump. Contact clinical/technical support if Pump appears to be operating incorrectly.

All patients should be given a Patient Manual and instructed to read it carefully.

The Pump must be used only by the person for whom it is prescribed.

The patient should never perform any function or push any button unless instructed by their health care professional.

Do not allow the Pump to get wet. If the Pump is immersed in any liquid, it must be replaced with a new Pump.

Transport and storage conditions: -7ºC to 70ºC (20ºF to 158ºF), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

Operating conditions: 10ºC to 43ºC (50ºF to 110ºF), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

Never attempt to open the Pump case. Only the battery cover may be removed when changing batteries. If the Pump is dropped, it must be replaced with a new Pump.

This Pump is not to be used for infusion of blood or blood products.

This pump is not to be used for infusion of life sustaining medications.

Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Dispose of batteries properly after use.

Safety hazards such as under infusion may be associated with external radio frequency interference (RFI) or electromagnetic radiation. Typical equipment which may generate such radiation include x-ray machines, MRI equipment, and any other non-shielded electrical equipment.

Failure to use the approved Sorenson Medical, Inc. remote BOLUS button could result in an inadvertent bolus dose.

The ambIT® PCA Pump Cassette is a sterile, disposable administration set.

- Carefully examine each Cassette before use. Make sure there are no damaged, or missing parts.
- Do not use a Cassette if the outer package is torn, punctured, wet or damaged.
- Do not touch sterile open end of tubing. Use aseptic technique.
- Do not re-sterilize Cassette.

Protection from air infusion:

- The solution must be provided in a non-vented, collapsible container.
- Remove all air from solution container and tubing before use.

Safety hazards are associated with the interconnection of other infusion systems. Refer to: Terry, Judy (Ed.), Intravenous Therapy, W. B. Sanders Co. 1995, pp 192–193.

The Cassette should not be used for infusion volumes greater than two (2) liters.

In order to minimize the possibility of infection, Cassettes should be changed in accordance with your institution's policies.

When the desired volume to be infused has been delivered, the empty solution container must be changed. Failure to do so may result in cessation of fluid delivery.

Before starting therapy, check that all connections are secure and there are no leaks in the fluid path.

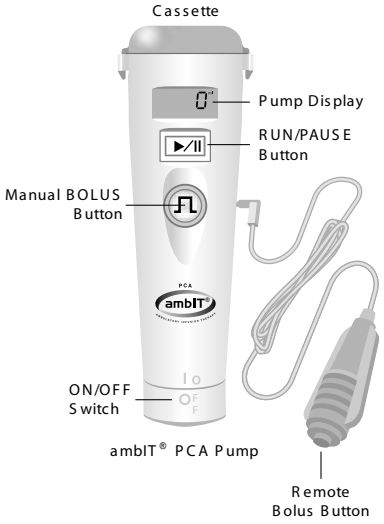
Bolus and infusion history reports should never take the place of good clinical judgement. Always perform a clinical evaluation whenever interpreting these reports.

Infusing viscous solutions (e.g. D25W) into high pressures (e.g. approaching 300mm Hg) may decrease volumetric accuracy.

1.3 Overview

The ambIT® PCA Ambulatory Infusion Pump is intended for the ambulatory infusion of fluids and medications. The Pump has simple controls that are easily operated by both caregivers and patients.

The clinician may select different delivery profiles which include, basal rate only, basal rate with PCA (Patient Controlled Analgesia) bolus or PCA bolus only.



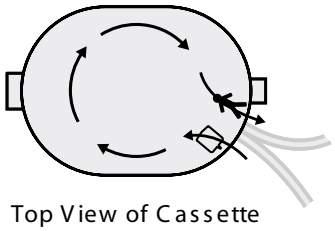
1.4 Product Description

ambIT® PCA Pump

The Pump program is determined by selecting the desired parameters during the Programming mode. A specific combination of pushing the Pump's buttons allows the user to access the Programming mode. This special combination of pressing buttons is designed to prevent inadvertent or unauthorized adjustments.

The RUN/PAUSE button is located just below the Pump display. This button is used to start, pause or resume the infusion and silence alarms. The RUN/PAUSE button toggles between Run and Pause. A blinking green Run light (inside the BOLUS button) and "ml" (volume infused) in the Pump display indicate the Pump is infusing.

If the infusion is paused, a blinking Pause symbol (II) in the Pump display and two (2) beeps every four (4) minutes indicate that the Pump infusion has been temporarily stopped. The BOLUS button is located below the RUN/PAUSE button. When pressed in Run mode, the Pump will deliver the programmed bolus dose. During bolus delivery, the green Run light (inside the BOLUS button) will double blink.The table in Section 7 of this manual completely describes each alarm and signal.

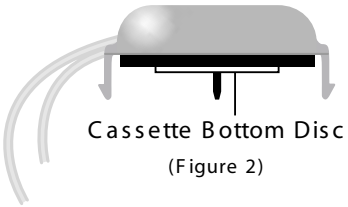


Top View of Cassette
(Figure 1)

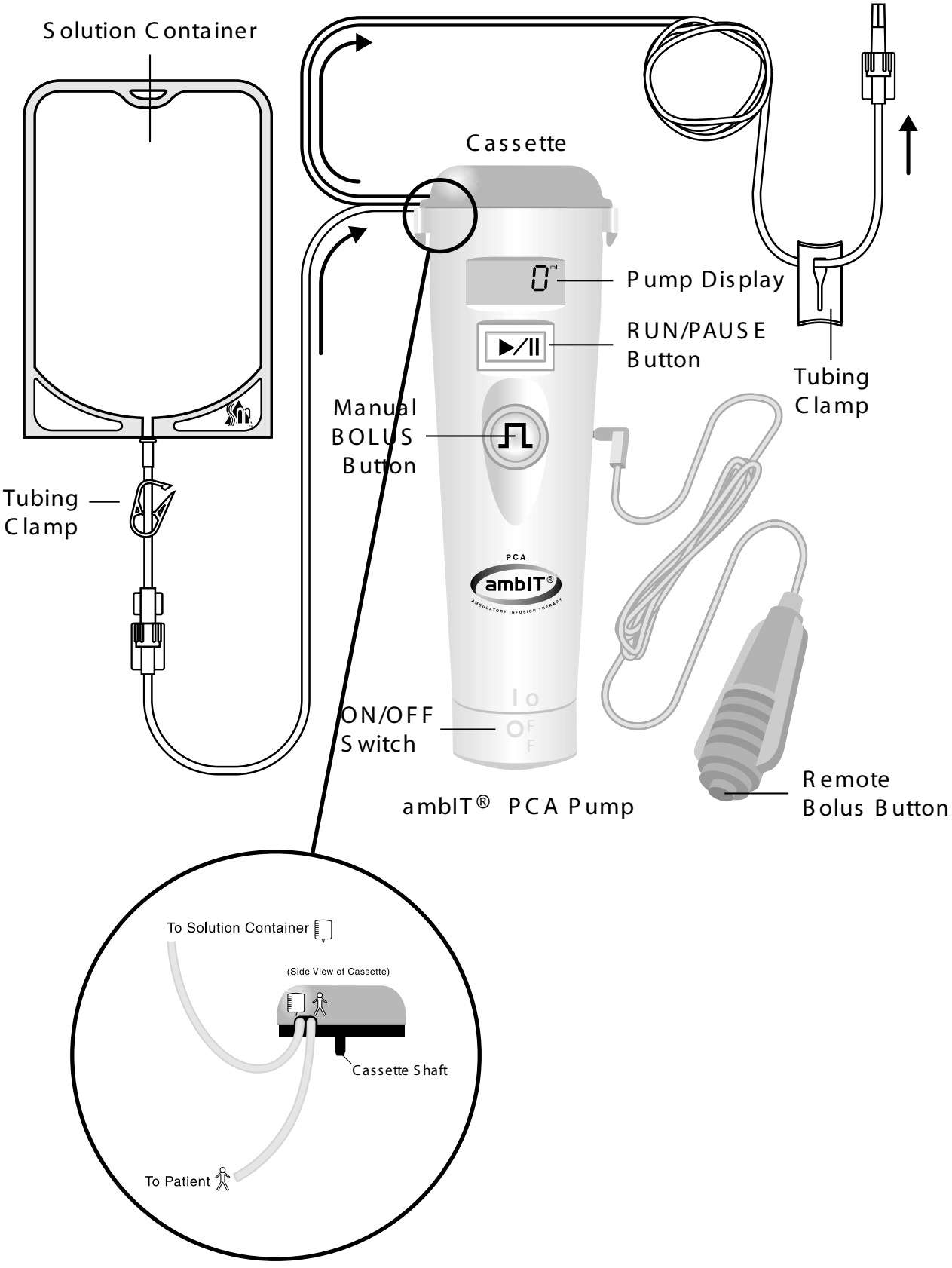
ambIT® PCA Pump Cassette

The Cassette contains a rotary mechanism that pumps the infusion solution at an accurate and controlled rate.

During Cassette priming, fluid will flow freely through the tubing (Figure 1). After priming, snapping the Cassette bottom disc into the body of the Cassette closes the fluid path preventing the free flow of fluid (Figure 2). When primed, the Cassette simply snaps onto the Pump.



Cassette Bottom Disc
(Figure 2)


Solution Container
Cassette
Pump Display
RUN/PAUSE Button
Tubing Clamp
Manual BOLUS Button
Tubing Clamp
PCA
ambIT®
ON/OFF Switch
ambIT® PCA Pump
Remote Bolus Button
To Solution Container
(Side View of Cassette)
Cassette Shaft
To Patient

(See Diagram on Page 8)

SECTION 2 SET UP

Warning: Protection from air infusion

- The infusion solution must be provided in a non-vented, collapsible container.
- Remove all air from solution container and tubing before use.

2.1 Required Materials

Infusion with the Pump requires the use of one of the following ambIT® PCA Pump Cassettes:

- ambIT® PCA Pump Cassette, Filter, Male Luer (1.2 micron air eliminating filter) Ref 220266
- ambIT® PCA Pump Cassette, Filterless, Male Luer, Ref 220267
- ambIT® PCA Pump Cassette, Filter, Spike (1.2 micron air eliminating filter) Ref 220140
- ambIT® PCA Pump Cassette, Filterless, Spike, Ref 220139
- ambIT® PCA Pump Cassette, Filter, Spike (0.2 micron air eliminating filter) Ref 220289

The Cassette is a sterile, disposable administration set. The upstream (short) tubing of the Cassette connects to a non-vented, collapsible solution container. Once the Cassette has been primed, the down stream extension (long) tubing of the Cassette connects to the patient's access device.

Note:
Accessories such as Medibag™ solution containers and carrying pouches may be added as required by the therapy.

2.2 Priming Cassette

Warnings:
Do not use a Cassette if the outer package is torn, punctured, wet or damaged.

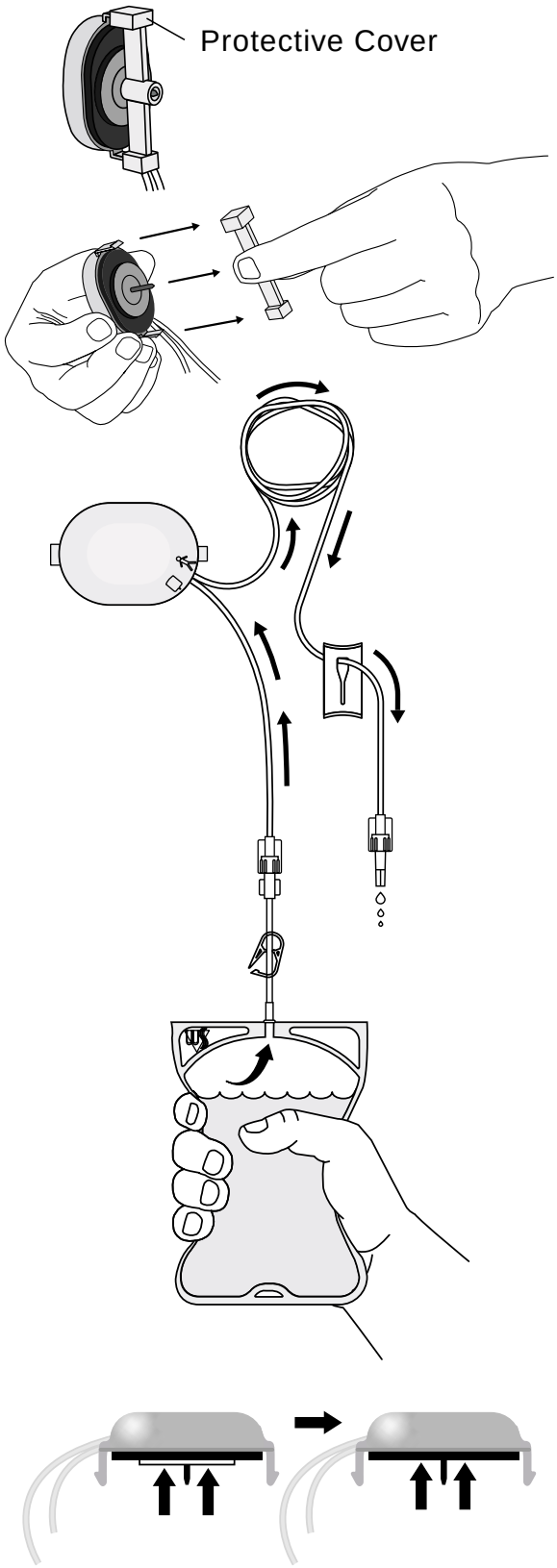
Do not touch sterile open ends of the tubing. Use aseptic technique.

Remove all air from solution container and tubing before use.

Be sure all connections are secure before starting therapy and check fluid path for leaks.

If filled solution container is not going to be used immediately, clamp the tubing and cap the female luer connector with the protective cap provided, to prevent contamination.

Always verify the Cassette bottom disc is snapped closed before attaching Cassette to Pump.



To prime the Cassette, follow these steps:

STEP 1
Remove protective cover from bottom of Cassette as shown.

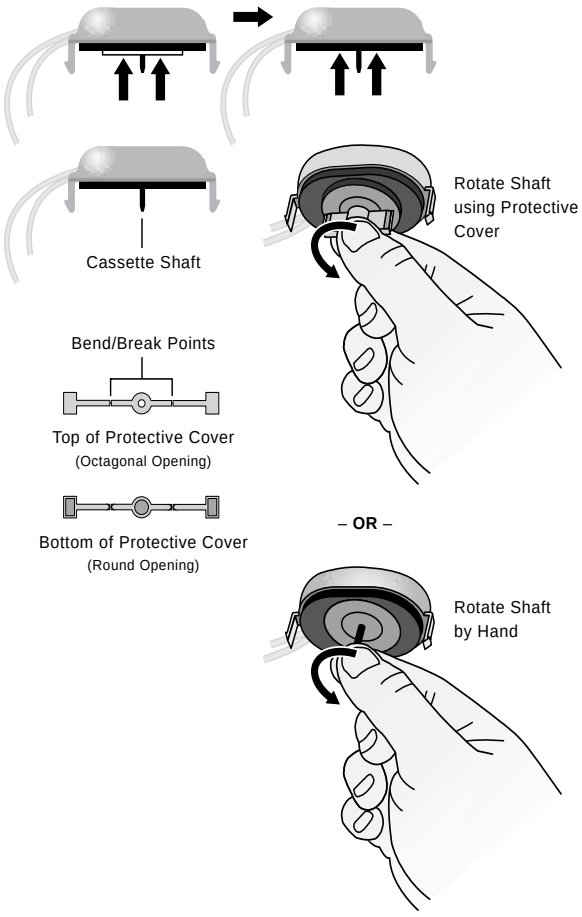
STEP 2
Connect the solution container to the Cassette using aseptic technique.

STEP 3
Release all clamps on tubing.

STEP 4
Invert the solution container to allow air to be evacuated first before priming the Cassette with fluid (see illustration).

STEP 5
Gently squeeze the solution to force fluid and air upward through the tubing and Cassette. Continue until the solution has completely filled the tubing and all air bubbles have been removed.

STEP 6
After priming, close the fluid path by snapping the Cassette bottom disc into the Cassette body. This will prevent free flow.



Note:
In the event the Cassette bottom disc is snapped closed before the priming process is complete, place the Cassette on the Pump (not attached to patient) and use the BOLUS button to complete the priming of the Cassette.

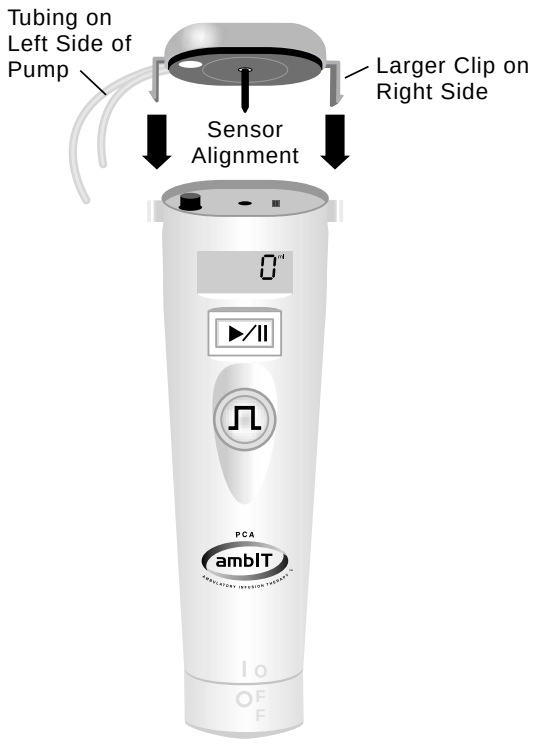
Important Information
To help ensure a successful infusion, please include the following steps:

1. Before placing the Cassette on the Pump:
   A. Prime the tubing (set aside the protective cover).
   B. Press the Cassette bottom disc into the Cassette Body as shown.
   C. Bend or break away the wings of the protective cover. Place the protective cover back on Cassette (insert Cassette Shaft into octagonal opening). Use protective cover to rotate Cassette Shaft counterclockwise three (3) or four (4) times.

Note:
The Cassette Shaft can also be rotated by hand.

2. Most “MA” alarms can be resolved by pressing the RUN/PAUSE button to silence the alarm and press it again to restart the infusion. If the alarm persists, contact Sorenson Medical, Inc.

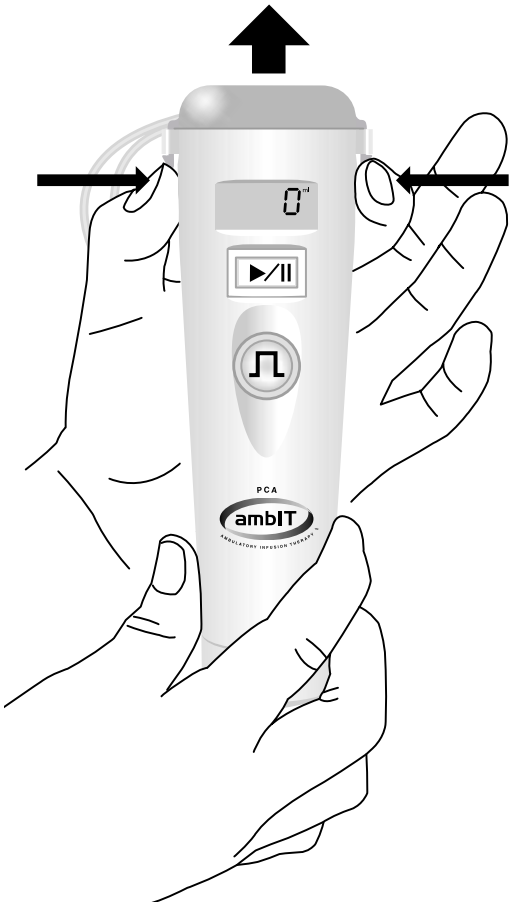
3. Make sure the patient is instructed on the proper use of the Pump.



ambIT™ PCA Pump

2.3 Attach Cassette To Pump

Insert the Cassette onto the top of the Pump, as shown. Gently squeeze tabs on Cassette to attach onto Pump.



2.4 Remove Cassette From Pump

To remove the Cassette, press both Cassette release tabs at the same time and lift the Cassette off the Pump

Caution:

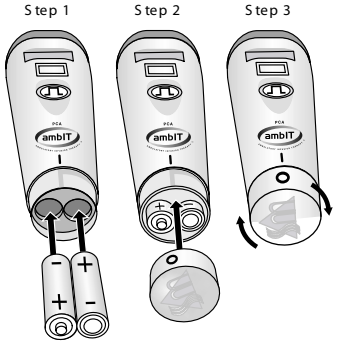
Do not remove Cassette while the green Run light is blinking. First place Pump in PAUSE.

2.5 Battery Installation and Replacement

The Pump is powered by two (2) AA alkaline 1.5V batteries.

Caution:
Sorenson Medical has not tested all rechargeable batteries with the pump; therefore we cannot ensure that a specific rechargeable battery will power the pump for a period of time. The battery condition and pump settings will determine how the battery will perform in the pump. For this reason the time before the low battery alarm occurs and the time between low and dead battery alarms is difficult to predict with non-alkaline batteries. We recommend you change the batteries at the end of each therapy.

The Pump memory is designed to retain program settings and infusion history for up to six (6) months without power. Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Do not store batteries in the Pump.



2.5.1 Battery Installation

To install batteries see illustration.

STEP 1: Insert batteries according to illustration

STEP 2: Place battery cover on Pump as illustrated in diagram (OFF symbol (O) on cover slightly to left of the (I) mark on Pump).

STEP 3: Rotate battery cover clockwise to the OFF (O) position

2.5.2 Battery Replacement

To replace batteries:

STEP 1: Place Pump in PAUSE

STEP 2: Rotate battery cover counterclockwise slightly to the left of the OFF (O) position until the cover stops or meets resistance.

STEP 3: Remove cover and replace batteries according to instructions in section 2.5.1.

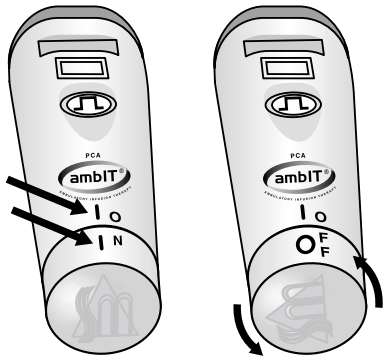
After battery replacement the Pump will return to the Pause mode.

Press the RUN/PAUSE button to review the current program settings.

Press the RUN/PAUSE button a second time to resume the current infusion program.

Warning:
When reinstalling batteries, always verify correct program settings.

Caution:
Verify the Pump is in PAUSE before removing batteries.



Power ON Power OFF Counterclockwise

2.6 ambIT® PCA Power ON and OFF

To power on the Pump, rotate the battery cover clockwise until the (I) mark lines up with the (I) mark on the Pump.

To power off the Pump:

STEP 1: Place the Pump in PAUSE.

STEP 2: Rotate the battery cover counterclockwise until the (O) mark lines up with the (I) mark on the Pump. (See illustration)

Note:
After the power on self-test, the Pump will beep twice and go into the Pause mode. The clinician can now program the Pump or resume current infusion settings.

SECTION 3
PROGRAMMING INSTRUCTIONS

3.1 General Information

The Pump must be programmed and have the history cleared before administering solution. The Pump has two (2) buttons, the RUN/PAUSE and the BOLUS buttons. A specific combination of pushing these buttons sets the Pump program.

Follow these steps to enter the Programming mode:

STEP 1: Place the Pump in PAUSE.

STEP 2: Press and hold down both the RUN/PAUSE button and the BOLUS button for two (2) seconds until one (1) beep sounds

STEP 3: “PRO” will appear in the pump display.

Next, the “ml/hr” will appear and blink in the Pump display. Remaining steps for programming the Pump are shown in Sections 3.2 - 3.6.

The Pump can be reprogrammed during infusion, without clearing the infusion history, by placing the Pump in Pause and entering the Programming mode. See Section 3.3 Programming Steps.

The Pump can be reprogrammed after clearing the infusion history (see Section 5.2 Clearing Pump Infusion History) by entering the Programming mode and selecting the desired parameters.

Note:

- The manual BOLUS button must be used to program the Pump.
- When attempting to program/reprogram the Pump, LOC will appear in the Pump display if the Pump program is in the Lock mode (see Section 6 - Patient Lockout).
- The Pump program must be unlocked for programming/reprogramming and clearing infusion History.

3.2 Program Parameters

The parameters that may be programmed into the Pump are as follows:

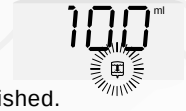
- Basal Infusion Rate: The constant infusion flow rate provided by the Pump. Rate is expressed in milliliters per hour (ml/hr).
- Bolus Volume: The amount of drug infused upon request by pressing the BOLUS button. Bolus volume is expressed in milliliters (ml).
- Bolus Lockout Time: The time period after the last bolus delivery in which another bolus is not allowed. Bolus lockout time is expressed in hours and minutes (HH:MM). The BOLUS button will not deliver a bolus during this time.

- Volume to be Infused: The total amount of fluid in the solution container to be infused. When this amount has been infused, the “Infusion Complete” alert (one (1) long tone followed by three (3) short beeps every four (4) minutes) will sound and the “Bag” icon in the Pump display will appear.

Warning:
When the desired volume to be infused has been delivered, and the “Infusion Complete” alert has sounded, the Pump will deliver a KVO rate (0.5 ml/hr) until the Pump is reset (history cleared) or turned off. If the basal infusion rate is less than 0.5 ml/hr the Pump will continue at the set basal rate.

The Pump should be programmed by a physician or under the direction of a physician. Patients should be instructed not to program the Pump or attempt to change the program.

3.3 Programming Steps

ACTION	SOUND	PUMP DISPLAY
To enter the Programming mode: From Pause mode, press and hold down both the **RUN/PAUSE** button and the **BOLUS** button for 2 seconds.	1 Beep	"PRO" displays for 2 seconds to indicate the pump is in programming mode. Basal flow rate is displayed in ml/hr.
Setting Basal Flow Rate: Press the **RUN/PAUSE** button to increase the rate or press the **BOLUS** button to decrease the rate (0–20). When the desired rate appears in the display, press and hold either the **RUN/PAUSE** button or the **BOLUS** button for 2 seconds to accept the rate.	1 Beep	Number left of decimal point flashes alternately with "ml/hr".
Repeat the same steps to set rate right of the decimal point (.0–.9).	1 Beep	Number right of decimal point flashes alternately with "ml/hr". Basal flow rate is established.
Setting Bolus Dose Volume: Press the **RUN/PAUSE** button to increase the volume or press the **BOLUS** button to decrease the volume (0–20). When the desired volume appears in the display, press and hold either the **RUN/PAUSE** button or the **BOLUS** button for 2 seconds to accept the volume.	1 Beep	Bolus dose volume is displayed in ml. Number left of decimal point flashes alternately with ml and bolus icon.
Repeat the same steps to set rate right of the decimal point (.0–.9).	1 Beep	Number right of decimal point flashes alternately with ml and bolus icon. Bolus dose volume is established.
Setting the Bolus Lockout Time: Press the **RUN/PAUSE** button to increase the time or press the **BOLUS** button to decrease the time. When the desired lockout time appears in the display, press and hold either the **RUN/PAUSE** button or the **BOLUS** button for 2 seconds to accept the lockout time.	1 Beep	Bolus lockout time is displayed in hours and minutes. hr:min is displayed with bolus, lock, and clock icon flashing. ***Note:*** If Bolus Dose Volume is set to "0" this step will be skipped. Bolus Lockout is established.
Setting the Volume to be Infused: Press the **RUN/PAUSE** button to increase the volume or press the **BOLUS** button to decrease the volume. When the desired volume appears in the display, press and hold either the **RUN/PAUSE** button or the **BOLUS** button for 2 seconds to accept the volume to be infused.	2 Beeps	Volume to be infused is displayed in ml with bag icon flashing. Volume to be infused is established. 
		Pump returns to Pause with Pause indicator flashing. ***Note:*** To confirm program settings (3.4), access Rx by pressing the **BOLUS** button one time. Pump will scroll through programmed settings and return to Pause.

To accept the current program settings in each step and not make any changes, press and hold the **RUN/PAUSE** and/or **BOLUS** buttons for 2 seconds until 1 beep sounds.

Note: Numbers are for example only.

3.4 Program Review

Caution:
After programming Pump, always verify the program by performing a program review.

To review the Pump program:

STEP 1: Place Pump in PAUSE.

STEP 2: Press the BOLUS button one (1) time.

"RX" will appear in the display and the Pump will scroll through each programmed parameter in the sequence shown on the table below. After the review, the Pump will return to Pause and be ready to begin or resume the infusion.

Note:
The remote BOLUS button may be used for Program Review.

Symbols	Parameter
ml/hr	Basal Flow Rate
Bolus icon ⎍ and ml	Basal Dose Volume
Bolus ⎍, Lock and Clock icons	Bolus Lockout Time
Bag Volume icon and ml	Total Volume to be Infused

3.5 Pump Delivery Profiles

Please refer to Section 3.1 General Information. The Pump can be programmed to provide three (3) delivery profiles: basal rate with PCA bolus, basal rate only, or PCA bolus only. Basal flow rates range from 0 ml/hr to 20 ml/hr and can be adjusted in 0.1 ml/hr increments. Bolus volumes range from 0 to 20 ml, in 0.1 ml increments. Refer to the table below for all possible program settings.

Available Program Settings	
Basal Flow Rate (ml/hr)	0 – 20 in 0.1 ml/hr increments
Bolus Dose Volume (ml)	0 – 20 in 0.1 ml increments
Bolus Lockout Time (HH:MM)	00:05, 00:10, 00:15, 00:20, 00:30, 00:45, 1:00, 1:30, 2:00, 4:00 8:00, 12:00
Volume to be Infused (ml)	25, 50, 75, 100, 150, 200, 250, 300, 350, 400, 450, 500, 600, 700, 800, 900, 1000

3.5.1 Basal Rate with PCA Bolus

To infuse a basal rate with a PCA bolus, set the infusion rate, bolus volume, bolus lockout time, and volume to be infused to the desired parameters.

3.5.2 Basal Rate Only

To infuse a basal rate only, select the basal infusion rate (ml/hr). Set the bolus dose volume at “0” followed by the volume to be infused.

Note:
If bolus volume is set at “0”, lockout time will not display.

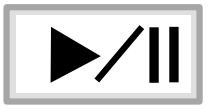
3.5.3 PCA Bolus Only

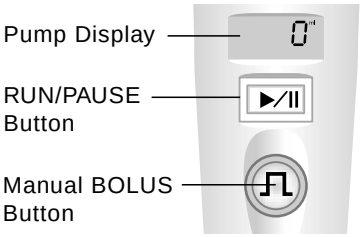
To infuse a PCA bolus only, set the basal infusion rate to “0”. Set the bolus volume and bolus lockout time followed by the volume to be infused.

3.6 Summary of Programming Controls

Activity	Steps	Audible	Visual
Program/ Reprogramming Pump	From Pause mode, press and hold down both the **BOLUS** button and the **RUN/PAUSE** button for 2 seconds	1 beep	“PRO”-Parameters can now be changed.
Review and verify program settings	While Pump is in Pause, press the **BOLUS** button	1 beep	“RX”-Display cycles through each programmed parameter
Review Infusion History	While Pump is in Pause, press and hold down the **BOLUS** button for 2 seconds	1 beep	“HX”-Display cycles through each Infusion History parameter
Clear Infusion History and begin new infusion	Upon entering the Infusion History (above), release and immediately hold down the **BOLUS** button again for 2 more seconds ***Note:*** Pressing the **RUN/PAUSE** button will repeat the same Pump program	1 beep	“HX 0”-Display shows “HX 0” to verify history has been cleared

SECTION 4
OPERATING INSTRUCTIONS



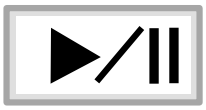


4.1 Start Infusion

Note:
Before starting infusion, the Pump must be programmed. See Section 3 Programming Instructions for details.

To begin an infusion, with the Pump in Pause, press the RUN/PAUSE button. The RUN/PAUSE button is located directly below the Pump display.

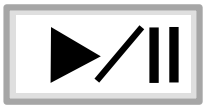
The green Run light (inside the BOLUS button) will start to blink and the “ml” (volume infused) will appear in the Pump display.



4.2 Pause Infusion

To PAUSE the infusion, press the RUN/PAUSE button. The Pump will beep two times, the green Run light will stop blinking and the Pause (ll) icon will blink in the Pump display. If left in Pause, the Pump will beep two (2) times every four (4) minutes.

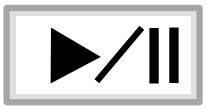
Note:
Pause temporarily stops the infusion. While in Pause, the infusion is delayed. This allows for changing the Cassette, solution container, or batteries.



4.3 Resume Infusion

To resume the infusion from Pause, push the RUN/PAUSE button.

The display will show the “ml” (volume infused) and the green Run light will start to blink. The infusion will resume at the same point as when the Pump was placed in Pause.



4.4 Silence Alarm

To silence an alarm, push the RUN/PAUSE button. When the alarm has been silenced, the Pump will remain in Pause. Once the cause of the alarm has been corrected, press the RUN/PAUSE button to resume the infusion.

Note:
If the Pump alarms due to downstream pressure and the cause of the alarm is corrected without intervention, the alarm will silence and the Pump will resume the infusion automatically.

4.5 PCA Bolus Activation

The PCA (Patient Controlled Analgesia) BOLUS button is located on the Pump directly below the RUN/PAUSE button. Every time the BOLUS button is pressed during the infusion, the Pump will beep once. If the bolus dose is permitted, the Pump will begin bolus administration. During bolus infusion, the green Run light will double blink. If the BOLUS button is pressed during the bolus lockout time, the pump will beep once, but no bolus will be delivered.

Note:

- BOLUS button is disabled when bolus volume is set to 0 ml.
- Flow rate during PCA bolus is 100 ml/hr.
- The BOLUS button is disabled if the volume to be infused has been delivered. During this time, if the BOLUS button is pressed, the "Infusion complete" alert will sound.
- A remote BOLUS button may also be used.
- Connect remote BOLUS button to the Pump before placing Pump in Run mode.

4.6 Summary of Operating Controls

To:	Steps to Take	Audible Indicator	Visual Indicator
Start Infusion	Program Pump, then Press **RUN/PAUSE** button	None	Green Run light blinks (inside **BOLUS** button) and "ml" (volume infused) is in Pump display
Pause Infusion	Press **RUN/PAUSE** button one time	2 beeps	Pause (**II**) icon flashing in display
Silence Alarm	Press **RUN/PAUSE** button one time	Alarm sound stops	Pause (**II**) icon flashing in display
Bolus Delivery	Press **BOLUS** button one time. ***Note:*** Patient may use manual or remote **BOLUS** button.	1 Beep	Green Run light double blinks

SECTION 5
INFUSION HISTORY REPORTS

5.1 Pump Infusion History

To obtain the Pump Infusion History:

STEP 1: Place Pump in PAUSE.

STEP 2: Press and hold down the BOLUS button for toe (2) seconds, until one (1) beep sounds and (HX) is displayed.

Note:
The remote BOLUS button may be used to review Infusion History.

The Pump will cycle through the following parameters:

Infusion History	**Visual Indicator**
Total volume infused including boluses in ml	ml
Total number of boluses actually delivered	No. and ⎍
Total number of bolus requests	No. and ⎍
Elapsed Time (Time pump has been in run mode since history was cleared.)	"🕘" and hr:min **After 100 hours, Pump will only display hours (not minutes)

The displayed parameters indicate history since the last time the Pump history was cleared as explained in Section 5.2.

5.2 Clearing Pump Infusion History

To clear the Pump Infusion History:

STEP 1: Place Pump in PAUSE.

STEP 2: Press and hold down the BOLUS button for two (2) seconds (obtaining the Infusion History mode).

STEP 3: Upon entering the Infusion History mode (HX), release the BOLUS button and immediately press and hold the BOLUS button again until (HX 0) appears in the Pump display. This indicates the clearing of the Pump Infusion History.

Note:

- The Pump program must be unlocked for programming/reprogramming and clearing Infusion History.
- When attempting to clear the Pump Infusion History, LOC will appear in the Pump display if the Pump program is in the Lock mode (see Section 6–Patient Lockout).
- The manual BOLUS button must be used to clear the Infusion History.

SECTION 6
PATIENT LOCKOUT

The Pump has been designed with patient lockout features:

LEVEL 1 - SOFTWARE – The steps required for entering the Pump program mode should not be revealed to the patient. This prevents the unauthorized tampering with the infusion parameters.

LEVEL 2 – ACCESS CODE – The Pump includes a patient lockout feature. The Lockout mode is accessed by following these steps:

STEP 1: Place Pump in PAUSE.

STEP 2: Enter the Pump's Program mode by pressing and holding down both the RUN/PAUSE and BOLUS buttons at the same time until one (1) beep sounds and "PRO" appears in the Pump display.

STEP 3: Release both buttons and again press and hold down both buttons (RUN/PAUSE and BOLUS) for two (2) seconds, until one (1) beep sounds and four (4) dash symbols appear in the display (_ _ _ _).

To Lock the Pump:

A lock code is entered into the Pump by entering a number in each digit space of the display, starting from the right.

STEP 1: Flashing 1st digit space.

STEP 2: Press the RUN/PAUSE button to increase the number, press the BOLUS button to decrease the number.

STEP 3: When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button for two (2) seconds until one (1) beep sounds.

STEP 4: Repeat steps 1-3 to program digits two through four (2-4).

Note:

- The clinician may program 1-4 digits into the Pump for the lock code.
- If programming only 1-3 digits into the Pump for the lock code, when the desired code is programmed (eg: 12 or 123), press and hold both the RUN/PAUSE button and the BOLUS button for two (2) seconds until one(1) beep sounds. This will accept the shortened code and lock the Pump program.
- After selecting the lock mode, the Pump will return to the Pause mode and the Lock icon will appear in the display. Current program settings can be resumed by pressing the RUN/PAUSE button.

To Unlock the Pump:

To unlock the Pump program, the clinician accesses the Lockout mode of the Pump, as described above. The pre-programmed code is re-entered into the Pump by entering a number in each digit space of the display, starting from the right.

STEP 1: Flashing 1st digit space.

STEP 2: Press the RUN/PAUSE button to increase the number, press the BOLUS button to decrease the number.

STEP 3: When the desired number appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button for two (2) seconds until one (1) beep sounds.

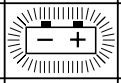
STEP 4: Repeat steps 1-3 to program digits 2-4.

Note:

- If entering only 1-3 digits for the lock code, when the code is programmed (eg: 12 or 123), press and hold both the RUN/PAUSE button and the BOLUS button for two (2) seconds until one (1) beep sounds. This will accept the shortened code and unlock the Pump program.
- After selecting the unlock mode, the Pump will return to the Program mode. The clinician can now either reprogram the Pump or verify and resume current program settings.
- In the event a code is forgotten, a default code of (5 _ _ 5) may be used to unlock the Pump program.
- The Pump program must be unlocked for programming/reprogramming and clearing Infusion History.

SECTION 7
ALARMS AND SIGNALS

7.1 Visible and Audible Alarm and Signal Table

Status	Icon	Visual Indicator	Audible Indicator	Comments
Pump Infusing Normally		Green Run light (inside **BOLUS** button) blinking, and “ml” (volume infused) in display.	None	Periodic movement of Cassette gears is normal.
Infusion Paused		“Pause” icon blinking in display. Green Run light off.	2 beeps every 4 minutes	
Infusion Complete		“Bag” icon illuminated	1 long tone followed by 3 short beeps. Repeats every 4 minutes	“Infusion Complete” alert will sound every 4 minutes.
Bolus Infusion		Green Run light (inside **BOLUS** button) double blinks. “Bolus” icon is displayed.	1 Beep	1 beep will sound every time the **BOLUS** button is pressed during Run mode.
Occlusion Alarm		“Alarm” icon illuminated with “OCL” in display	Constant Beeping	Press **RUN/PAUSE** button to silence alarm. Press **RUN/PAUSE** button to restart Pump. If unable to resolve (silence) alarm, contact health care professional.
Cassette not Attached to Pump		“MA” and “Alarm” icon	Constant Tone	Press **RUN/PAUSE** button to silence alarm. Gently press on top of Cassette to ensure proper placement. Resume infusion.
Low Battery		“Battery” icon blinking	5 short beeps every 4 minutes	Replace batteries as soon as possible.
Dead Battery		“Battery” icon, “Alarm” icon illuminated	Constant Tone	Press **RUN/PAUSE** button to silence alarm. Alarm and battery icons will remain on. Replace batteries immediately.
Malfunction		“MA” and “Alarm” icon illuminated	Constant Tone	Immediately close tubing clamp. See Section 8– Troubleshooting.

SECTION 8
TROUBLESHOOTING

8. Troubleshooting

Problem	Resolution	Reference
Cassette will not prime	¥Verify that tubing clamps are open ¥If spike set is used, verify that spike is completely inserted into solution container ¥Verify that Cassette bottom disc has not been snapped into the Cassette body	Section 2
Cassette will not attach to Pump	¥Verify proper Cassette placement onto Pump ¥Verify Cassette bottom disc has been snapped into Cassette body	Section 2
No display	¥Insert fresh batteries ¥Verify proper battery placement ¥Verify Pump power is in the ÒONÓ position	Section 2
Constant beeping during infusion	Fluid path occlusion ¥Verify that tubing clamps are open ¥Check access device patency ¥Check for kink in tubing	Section 4
Continuous tone	Malfunction ¥Possible dead battery alarm, replace batteries (battery icon visible). ¥Press on Cassette top to ensure proper placement. ¥Check Cassette - Remove Cassette from Pump. - Rotate Cassette spindle 1 time. - Replace Cassette on Pump. ¥Press RUN/PAUSE button to resume infusion. ¥If ÒMAÓ continues: - Immediately close tubing clamp. - Manufacturer's service/assistance may be required.	
Blood backed into tubing	¥Verify Pump is in Run Mode ¥Attempt to clear tubing by delivering a Bolus ¥If unable to clear tubing by delivering a Bolus, close tubing clamp and replace Cassette. ¥If situation continues, manufacturerÕs service/assistance may be required.	

SECTION 9
SPECIFICATIONS

ambIT® PCA Pump - Basal Rate and/or PCA Bolus with Infusion History Report

Volumetric Accuracy	± 6%
Maximum Basal Flow Rate	20 ml/hr
Minimum Basal Flow Rate	.1 ml/hr
Bolus Delivery Rate	100 ml/hr
Stroke Volume	50 microliters
Basal Flow Rates	0 to 20 ml/hr in .1 ml/hr steps
Bolus Dose Volumes	0 to 20 ml in .1 ml steps
Bolus Lockout Times	00:05, 00:10, 00:15, 00:20, 00:30, 00:45, 1:00, 1:30, 2:00, 4:00, 8:00, 12:00
Volumes to be Infused	25, 50, 75, 100, 150, 175, 200, 250, 300, 350, 400, 450, 500, 600, 700, 800, 900, 1000
Pump Mechanism	Microprocessor controlled rotary peristaltic
Maximum Infusion/Occlusion Pressures	25 +/- 12 psi
Maximum Activation Time of Occlusion Alarm (minimum rate) at Minimum Occlusion Pressures	4 Hours
Maximum Activation Time of Occlusion Alarm (intermediate rate) at Maximum Occlusion Pressures	90 Seconds
Dimensions	2.16 in. x 1.4 in. x 6.875 in (55 mm x 36 mm x 175 mm)
Weight	4.7 ounces (133.2 grams) without batteries 6.4 ounces (181.4 grams) with batteries
Power Supply, Internal	2 each AA alkaline 1.5V batteries (2 days @ 10 ml/hr)
Power Supply, External	None
Operating Controls Button	RUN/PAUSE Button, BOLUS Button, ON/OFF Switch, Remote BOLUS Button
Display, Audible Alarms, Signals and Reports	• Run Indicator Light • Bolus Infusing • Pause Indicator • Obstruction-Downstream (25 +/- 12 psi) • Cassette Not Mounted on Pump • Low Battery • Dead Battery • Malfunction • Bolus Request • Infusion Complete
History Reports	• Volume Infused • Bolus History–Number of Boluses Delivered • Bolus History–Number of Bolus Requests • Elapsed Time
Delivery Profiles	• Basal Rate + PCA Bolus • Basal Rate • PCA Bolus Only

Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

SECTION 10
DELIVERY RATE ACCURACY

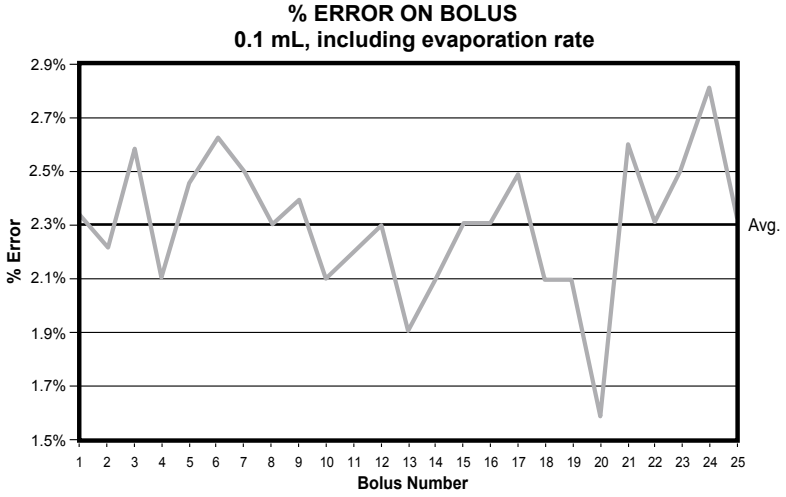
The following representative trumpet curves show flow rate deviation from the programmed rate over time. The curves give the percent error under different conditions of flow rate, delivery head pressures and for different periods of time. These graphs are applicable for all ambIT® PCA Pump Cassettes.

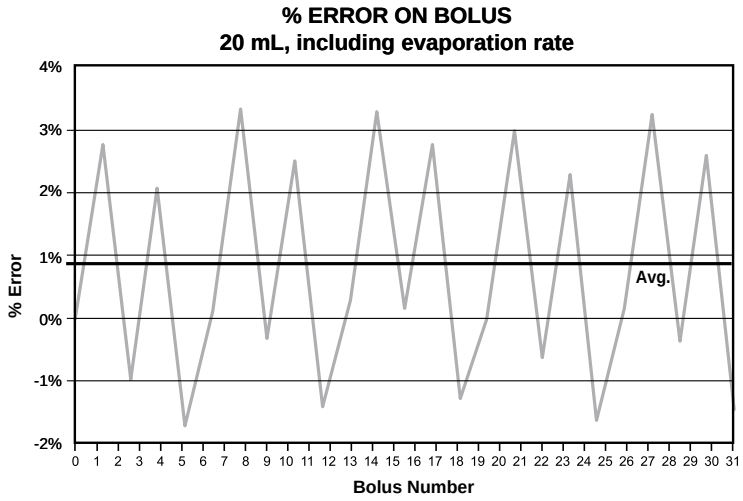
When the time interval over which the accuracy is measured is shortened, all pumps show considerable variations of flow pattern. For instance, all pumps that have pulsed flow (such as peristaltic, diaphragm, and piston pumps) show an increase in volumetric accuracy as the observation window is expanded. The graphs that follow show this increase in volumetric accuracy.

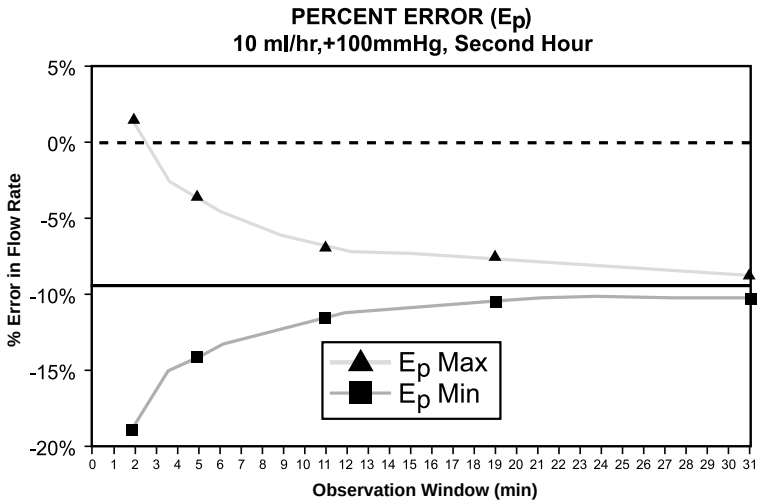
The ambIT® PCA Pump uses a rotary peristaltic mechanism to deliver fluid. The Pump completes a stroke in about a second, then is idle until the next stroke is due. Thus the instantaneous rate error may exceed 6%.

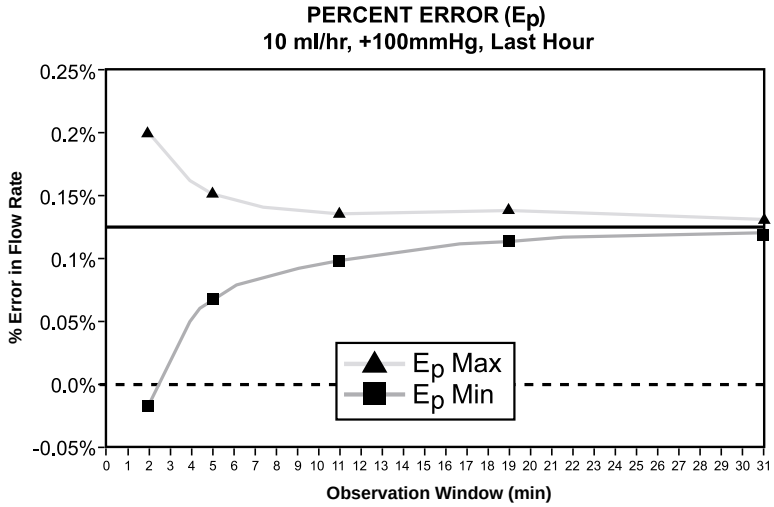
The user is directed to be aware of the delivery profile of the Pump as shown in the graphs below and on the next three (3) pages to ensure that it is acceptable for the drug being infused, its concentration and rate of delivery.

Pulling fluid from a syringe will affect volumetric accuracy.

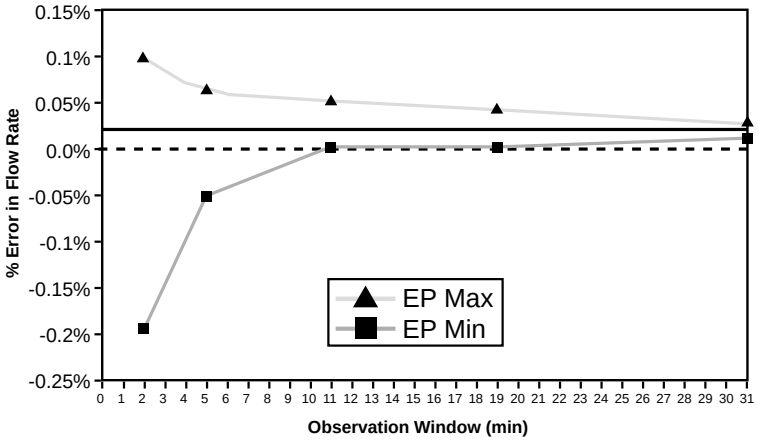



% ERROR ON BOLUS
20 mL, including evaporation rate
4%
3%
2%
1%
0%
-1%
-2%
% Error
Avg.
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Bolus Number

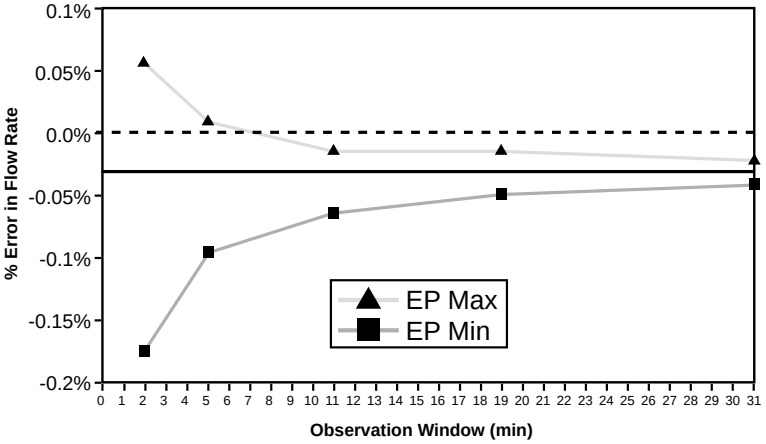

PERCENT ERROR (Ep)
10 ml/hr,+100mmHg, Second Hour
5%
0%
-5%
-10%
-15%
-20%
% Error in Flow Rate
Ep Max
Ep Min
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Observation Window (min)


PERCENT ERROR (Ep)
10 ml/hr, +100mmHg, Last Hour
0.25%
0.2%
0.15%
0.1%
0.05%
0.0%
-0.05%
% Error in Flow Rate
Ep Max
Ep Min
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Observation Window (min)

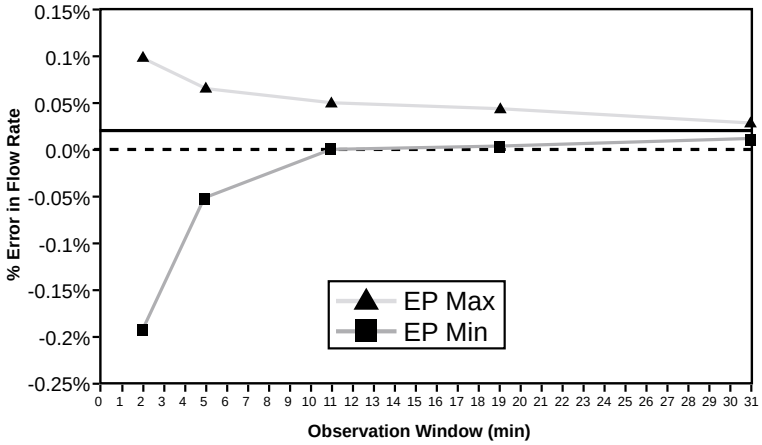
PERCENT ERROR (EP)
10 ml/hr, -100mmHg Last Hour



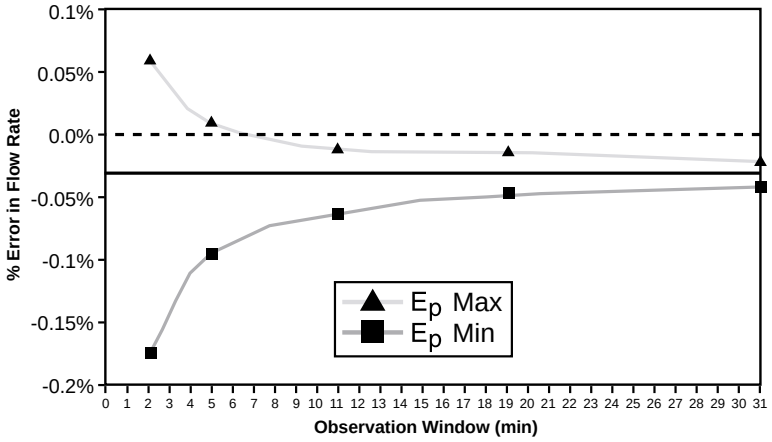
PERCENT ERROR (EP)
10 ml/hr, Last Two Hours



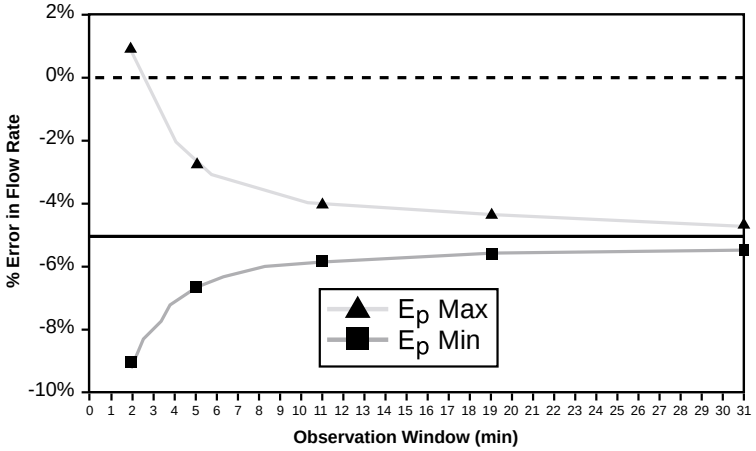
PERCENT ERROR (EP)
10 ml/hr, Last Hour



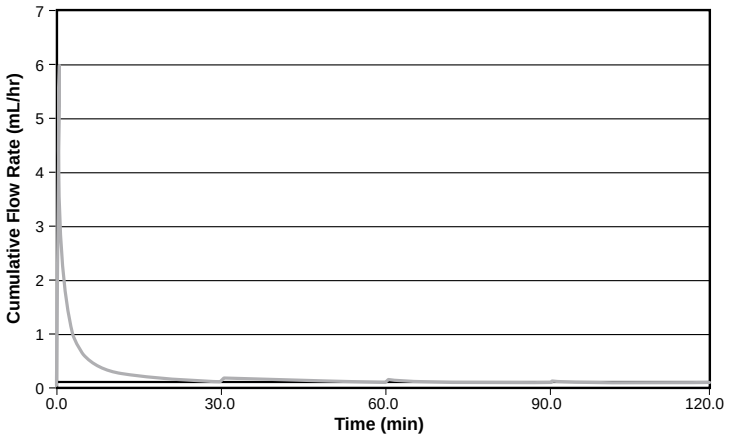
PERCENT ERROR (E_p)
10 ml/hr, Last Hour, Supply 0.5 m below Pump



PERCENT ERROR (E_p)
20 ml/hr, Second Hour



FLOW RATE
0.1 ml/hr, Last 2 Hours



SECTION 11
GENERAL CARE INSTRUCTIONS

The patient should be careful to protect the Pump at all times. The Pump should not be dropped, stored in freezing -7ºC (20ºF) temperatures, left in direct sunlight or exposed to excessive heat 70ºC (158ºF). The Pump should only be operated between 10ºC and 43ºC (50ºF and 110ºF).

Pump and components should be stored in a dry, cool place until used.

The Pump can be cleaned by wiping its surface with a slightly damp cloth. Use only mild detergent soaps.

To disinfect the Pump, use a cloth slightly dampened with any of the following:

- A fresh solution of one (1) part household bleach to nine (9) parts water.
- 70% Isopropyl alcohol.
- Equivalent disinfectant product.

Warning:
Pump failure may be caused by the application of cleaning solutions other than those recommended by the manufacturer.

Do not immerse the Pump or sterile Cassette in any cleaning solutions.

Note:
For storage and transporting the Pump, a cap should be placed on the Pump to protect the delicate pressure switch.

11.1 Warranty Information

The ambIT® PCA Pump is covered by a manufacturer's warranty to be free from defects in materials and workmanship for six (6) months from date of purchase. During this time, opening the Pump for any reason except for changing the batteries voids this warranty. The ambIT® PCA Pump contains no serviceable parts.

This warranty will not apply to ambIT® Pumps that have been in Sorenson Medical's judgement damaged whole or in part due to misuse, abuse, negligence, alteration, improper installation, dropped or otherwise used in a manner inconsistent with it's labeling and packaging.

To obtain warranty service, the pump and cassette must be returned to Sorenson Medical, Inc. postage prepaid. The replacement of a pump and cassette will not extend the original term set forth above.

SECTION 12
CUSTOMER ASSISTANCE

For Customer Assistance, please contact your distributor or Sorenson Medical, Inc. at:

Sorenson Medical, Inc.
1375 West 8040 South
West Jordan, Utah 84088-8320, USA

Toll Free: (877) 352-1888
Phone: (801) 352-1888
Fax: (801) 352-1818

e-mail: service@sorensonmedical.com
Web Site: www.sorensonmedical.com

European Representative:
Medical Technology Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

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SORENSON MEDICAL

FINDING BETTER WAYS TO CARE FOR PEOPLE™